Kentucky Women's Cancer Screening Program General Provider Contract Requirements Fiscal Year 2011

Rev. 02/23/2010

- 1) The Contractor shall follow the Public Health Practice Reference Cancer Screening Follow-Up section for relevant guidelines included in this contract document along with any revisions or updates made during the contract period.
- 2) Payment under terms of this contract is payment in full for all services covered by the Kentucky Women's Cancer Screening Project or other services if specified by the Health Department in this contract. The patient shall not be billed by the Contractor for any services covered by the Health Department. For services not covered by the Health Department, when performed concurrently, separate reimbursement shall not be made to the Contractor for procedures and supply items that have been determined by the department to be incidental, integral or mutually exclusive to another procedure. Procedures and supply items that are incidental and integral to procedures, such as the performance of services in the hospital outpatient department, are included in a base payment rate. "Incidental" means that a medical procedure is performed at the same time as a primary procedure and: (a) Requires few additional physician resources; or (b) Is clinically integral to the performance of the primary procedure. "Integral" means that a medical procedure represents a component of a more complex procedure performed at the same time.
- 3) Payment shall be provided at the LHD negotiated rates for CPT codes reimbursed by the Kentucky Women's Cancer Screening Program included as an attachment to this contract. Payment will be submitted upon receipt of appropriate billing AND provision of clinical findings to the Health Department. The Contractor agrees to provide medical record documentation to the Health Department within thirty days of procedure.
- 4) The Contractor agrees to provide information required for the Health Department to meet state and federal service reporting requirements in order to ensure quality and timely patient care and secure funds to pay for services covered in the attached list.
- 5) The Contractor must return all written results no more than 21 days after receipt of Pap test specimens or the patient's mammogram/ultrasound screening. Any biopsy results (if applicable in contract) should be returned to the Health department within two (2) weeks (14 working days) of receipt of specimen.
- 6) The Contractor must contact an RN, ARNP, or PA at the local health department by telephone within twenty-four working hours when any Pap specimen is determined to be categories 5, 6, 7, or 9, according to the reporting categories listed in the Pap/Pathology Requirements which is based on the Bethesda system. This notification shall also include a three-day turnaround for mailing these results.
- 7) The Contractor must contact an RN, ARNP, or PA at the local health department by telephone within twenty-four working hours when a mammogram result is a Bi-Rads 4 or 5 according to the reporting categories listed in the Mammography Requirements which is based on the American College of Radiology reporting system. This notification shall also include a three-day turnaround for mailing these results.
- 8) The Contractor must provide timely telephone consultation by a pathologist (Pap/Pathology services) or radiologist (radiology services) when the Health department needs more information about results.

MINIMAL REQUIREMENTS FOR A CANCER SCREENING VISIT

ASSESSMENT	INITIAL VISIT	ANNUAL VISIT
Comprehensive Health History to include:		
Family history of breast/genital/colon cancers	Required	Required
• LMP or date of menopause	(Health History and	(Interval Health
Contraceptive method if childbearing age	Physical Examination	History and Physical
Documentation of HRT if menopausal	Form CH-13)	Examination
Date of last Pap/mammogram and results	,	Form CH-14)
Previous abnormal Pap, diagnostics, treatments		,
Previous breast problems, diagnostics, treatments		Update with CH-13
Assessment for breast/cervical cancer risk factors		every 3 years
Physical Examination to include:		
Documentation of general appearance and mental status		
Height/Weight		
Blood pressure		
Clinical breast examination (Using MammaCare® Technique)	Required	Required
Pelvic examination that includes visualization of the vulva,		1
vagina, cervix, and thorough bimanual including adnexa		
• Rectal exam (age 50 and as indicated for others)		
Other as needed		
Laboratory: * see recommendations per ACS (p. 9, c.1)	D 1 1/1	TD 1 1/1
• Pap test (may be done earlier at clinician's discretion)	Required*	Required*
• Fecal occult blood testing (ages 50 and older)		
o 3 kits given with instructions	Required	Required
o If positive, refer to M.D.	7	1
Hemoglobin	Recommended	If indicated
Blood glucose and Cholesterol	If indicated by	If indicated by
	history/exam	history/exam
STD testing	If indicated by	If indicated by
	history/exam	history/exam
Referral for annual mammogram (age ≥ 40)	Required	Required
Counseling: (Documentation in medical record required)	•	•
- ACH-40 ("Improving Health for Women") – CSEM		
given/counseled and patient verbalized understanding		
Monthly BSE/Annual CBE		
Pap/Mammogram rescreening		
Regular exercise		
• Adequate diet (low fat, high fiber, 5 fruits/vegetables)		
Osteoporosis/prevention and bone density testing	D : 1	D : 1
Risks/Benefits of HRT if menopausal	Required	Required
Contraception if needed		
Smoking risks/cessation, and referral		
Immunization needs/update		
• STD risk counseling if indicated		
• Ovarian Cancer Screening at age 50 (age 25 if family history)		
(Locations: UKMC; Hardin, Mason, Floyd, McCracken, and		
Pulaski County Health Centers) call 1-800-766-8279 for appt.		
Documentation of Return Clinic Appointments	Required	Required
Follow-up of Abnormal Test Results	Required	Required
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KENTUCKY'S WOMEN'S CANCER SCREENING PROGRAM OVERVIEW

Public health has a unique opportunity to educate women on the benefits of early detection of breast and cervical cancer with self-breast examination, clinical breast examination, and pelvic examination with Pap test screening. Early detection of breast and cervical cancer with a corresponding decrease in mortality is dependent on periodic rescreening.

A woman may be eligible for low cost breast and cervical cancer screening through the Kentucky Women's Cancer Screening Program (KWCSP) if she meets the following requirements: 21 to 64 years of age, household income less than 250% of the current annual federal poverty guideline, and has no third party payer source (no Medicare, no Medicaid and no private health insurance).

Women who receive cancer-screening services should be counseled on the importance of rescreening at recommended intervals. Services provided through the program include female adult preventive visits, cancer screening, diagnostic evaluation, patient education, and case management. All providers including contracted providers who receive state or federal funds from this program are expected and held accountable to abide by the written protocols. Protocols are based on grant requirements and the recommendations of the Medical Advisory and Breast Cancer Advisory Committees.

SCREENING SERVICES

A licensed physician, nurse practitioner, or physician assistant are the preferred providers of cancer-screening services. However, if a preferred provider is unavailable, an R.N. who has completed and received certification from the DPH approved Breast and Cervical Cancer training course may provide cancer-screening services to meet the minimal requirements of the program. If the DPH adult physical assessment course has been completed as well, the nurse may also offer full adult preventive screenings.

Breast and Cervical Cancer services may be provided as part of the complete adolescent or adult preventive visit *or* as an evaluation and management (E/M) office visit if the services provided only satisfy the minimal requirements of the program.

A patient shall be counseled and encouraged to receive complete breast and cervical screenings when applicable. However, the patient has the right to refuse any part of her screening. Refusal of either breast or cervical services will not make her ineligible for the KWCSP or BCCTP.

An annual pelvic examination is considered a component of cancer screening services. Only professionals trained in pelvic examination should be providing cancer-screening services. Screenings must be scheduled with providers who can provide the full range of services, including the bimanual examination and rectal examination. It is not acceptable for the LHD to refer a patient to an outside provider or have the patient return to clinic on another day for the completion of the pelvic examination with a different provider.

The preceding page is a matrix detailing the required services needed to meet the minimal requirements for a cancer-screening visit. See the matrix on page 1 under the tab "Preventive Guidelines-Adult" for the full adult preventive visit requirements.

REQUIREMENTS FOR ACCEPTING FOLLOW-UP REFERRALS FROM PROVIDERS

Healthcare providers should be encouraged to refer uninsured women to the local health department as soon as possible to determine eligibility for the Kentucky Women's Cancer Screening Program (KWCSP).

In the event a KWCSP *eligible* woman presents to the LHD for cancer-screening services, but has had a physical examination within the past 6 months that included CBE, Pelvic, and Pap test from another healthcare provider, the following are requirements of the Kentucky Women's Cancer Screening Program.

- 1. The woman must meet the eligibility requirements of the program and provide consent for services.
- 2. The patient is responsible for bringing her records at time of visit or having them sent to LHD prior to the visit. This will enable the LHD provider to assess if all the minimum requirements were met. These records must include copies of the actual physical examination (including CBE and pelvic examination) and a copy of the Pap test result as well as any other pertinent laboratory work such as stool for occult blood, hemoglobin, blood sugar, and cholesterol results. (A note from a physician such as "normal CBE needs mammogram" is not acceptable for medical record documentation).
- 3. The comprehensive health history (CH-13) must be completed and reviewed with the patient. The height, weight, and blood pressure should be obtained and recorded.
- 4. If the physical examination portion of the visit was completed elsewhere (within past 6 months) the nurse or clinician shall document on the physical exam form (back of CH-13) "See incoming records for the physical examination."
- 5. If the provider has failed to provide documentation of ANY of the minimal requirements on the patient, the LHD is responsible for completing these components prior to referral for screening or diagnostic services.
- 6. CBE must be performed at LHD if done >30 days prior to visit. It is imperative to know if the breast exam is normal or abnormal prior to determining if a screening or diagnostic mammogram is indicated.
- 7. It is the responsibility of the LHD to educate providers as to the minimal referral requirements of the program in order to accept patients for screening and possibly follow-up diagnostic services.

BREAST CANCER SCREENING & FOLLOW-UP

Early diagnosis of breast cancer offers women more treatment options and greatly reduces mortality. Early diagnosis is aided by the triad of monthly breast self-exam, annual clinical breast exam, and if age appropriate, regular mammography screening.

A. BREAST CANCER RISK FACTORS:

- 1. Female age 40 or older
- 2. First degree relative (mother, sister, daughter) with history of breast cancer before the age of 50 (premenopausal)
- 3. Personal history of a benign breast condition
- 4. Early menarche (prior to age 12)
- 5. Late menopause (after age 52)
- 6. No pregnancies or first pregnancy after age 30
- 7. Obesity and a high fat diet may also contribute to the development of breast cancer

B. BREAST SCREENING HISTORY:

- 1. Include dates and results of previous mammograms
- 2. Elicit personal history of breast symptoms including pain, tenderness, nipple discharge, palpable mass, or skin changes
- 3. Document any personal history of breast cancer, and previous biopsies or treatments
- 4. Screen for risk factors (listed above)

C. CLINICAL BREAST EXAMINATION AND MAMMOGRAPHY

- 1. All females should be taught monthly BSE beginning at age 20. Counseling shall be documented in the medical record at the initial and annual visits.
- 2. A clinical breast exam is recommended annually on all females beginning at age 20.
- 3. The required method for performing the clinical breast exam and teaching BSE is the MammaCare Method® using the principles of positioning, three levels of palpation, and recommended search patterns.
- 4. Routine screening mammograms will begin at age 40 and are recommended on an annual basis. In menstruating women, the mammogram should be scheduled about 2 weeks after the LMP.
- 5. Women age 30 and older with an *abnormal clinical breast* examination should be referred for a *diagnostic mammogram*. If the woman is under the age of 30, an *ultrasound* is usually preferred as a substitution for the mammogram due to the typically dense breast tissue; however the radiologist may choose to do a diagnostic mammogram in this age group if the breasts are not dense.
- 6. Women with a family history (mother, sister, or daughter) of pre-menopausal breast cancer (before the age of 50) and with a NORMAL CBE should begin yearly screening mammograms 10 years earlier than family member's breast cancer diagnosis (no younger than age 25). If patient unable to remember 1st degree family member's age, begin screening mammogram at age 35.
- 7. Women that have been diagnosed with either of 4 lesions; atypical hyperplasia, radial scar, papillomatosis, or lobular cancer in situ by biopsy, will need to begin annual screening mammograms.

BREAST CANCER SCREENING & FOLLOW-UP

(continued)

- 8. Women with breast implants should be scheduled for an annual screening mammogram beginning at age 40 unless clinical complaint (i.e., pain in breast).
- 9. Women that have had chest wall radiation will need to begin annual screening mammograms 10 years after radiation completed (no younger than age 25).
- 10. Women post mastectomy will need annual diagnostic mammogram.

D. SURGICAL REFERRALS

- Women with an abnormal CBE must be referred for surgical consultation regardless of diagnostic
 mammogram or ultrasound results unless CBE is done by radiologist and found to be negative/benign.
 Documentation by the radiologist shall be required. (Benign changes such as fibrocystic changes or
 nodularity should not be considered an abnormal CBE).
- 2. Any patient with a *bloody* nipple discharge (unilateral or bilateral) requires a referral to a surgeon for evaluation.
- 3. Any patient with a *spontaneous* (without nipple stimulation) and/or *unilateral* nipple discharge requires a referral to a surgeon for evaluation.
- 4. Bilateral non-bloody discharge that occurs only with nipple stimulation does not need referral to a surgeon. This type of nipple discharge may be due to fibrocystic changes (usually greenish), hormonal imbalance, pregnancy, lactation, and some medications (oral contraceptives, phenothiazides, anti-hypertensives, tranquilizers). If the clinician (MD or ARNP) determines the need for further evaluation of this type of nipple discharge, it typically is to either a gynecologist or endocrinologist.
- 5. If a patient presents with a "breast lump" that she has discovered on BSE but both the CBE and mammogram (or ultrasound) are normal, she does not need a referral to a surgeon.

E. PATIENT EDUCATION ON BREAST HEALTH

- 1. Counseling with documentation at the initial and annual visits shall include teaching BSE using the MammaCare method, individual breast cancer risk factors, and the importance of annual CBE with regular mammogram screenings if age appropriate.
- 2. Patients with either an abnormal CBE or mammogram result will have documented counseling done as appropriate.

F. FOLLOW-UP

- 1. Patients with an abnormal mammogram or ultrasound result shall be notified by the health department within 10 working days of receiving the result or within 30 days of the procedure, whichever comes first.
- 2. Referrals for a surgical consult, requested additional mammography views, or request for a breast ultrasound must be made within 3 weeks (21 days) of abnormal CBE or receipt of abnormal mammogram.
- 3. A final diagnosis must be made within 60 days of the abnormal CBE or abnormal mammogram result (from date screened).
- 4. Copies of results from consults & diagnostic procedures (including pathology reports) will be received and placed in the medical record within 60 days of the consult or diagnostic procedure.
- 5. The month and year the next mammogram is due will be documented on the CH3A.

G. TREATMENT

- 1. Patients that have been screened/diagnosed through KWCSP may be eligible for the treatment fund (BCCTP) if diagnosed with pre-cancer/cancer of breast. For more information and forms related to BCCTP, please refer to their website at http://chfs.ky.gov/dms/bcctp.
- 2. Verify patient's identity by viewing the patient's driver license. Contact the Department for Medicaid Services at 502-564-6204 for citizens born in Kentucky to obtain verification of citizenship. Other patients will need to contact Vital Statistics in their state of birth in order to obtain an original birth certificate. A passport may also be used for documentation of both identity and citizenship. For more information about the citizenship documentation requirement, go to:
 - http://www.cms.hhs.gov/MedicaidEligibility/ProofofCitizenship
- 3. Complete Pre-screening Eligibility Form.
- 4. Complete application and call Medicaid for confirmation number.
- 5. Enter per Web application (like P.E.). The original signed application, Pre-screening Eligibility Form and proof of identity and citizenship should be maintained in the patient's chart in the administrative section.

H. BI-RADS CLASSIFICATION OF MAMMOGRAM RESULTS AND MANAGEMENT

Category 0: Assessment Incomplete

This category indicates the need for additional imaging, which will be recommended by the radiologist or old films required for comparison.

Category 1: Negative

Recommendation should be made for routine follow-up according to the screening guidelines. Notify the patient when it is time for re-screening.

(Refer to surgeon if CBE is abnormal)

Category 2: **Benign Finding**

Recommendation should be made for routine follow-up according to the screening guidelines. Notify the patient when it is time for re-screening.

(Refer to surgeon if CBE is abnormal)

Category 3: Probably Benign

Follow-up should be provided according to the radiologist's recommendation. Usually the radiologist will recommend a repeat mammogram in six months. Counsel the patient on the results of the mammogram and provide a re-screening appointment. (Refer to surgeon if CBE is abnormal)

Category 4: Suspicious Abnormality

A biopsy should be considered. Refer to a surgeon for further evaluation. Counsel the patient on the results of the mammogram and assure that arrangements are made for the surgical consultation.

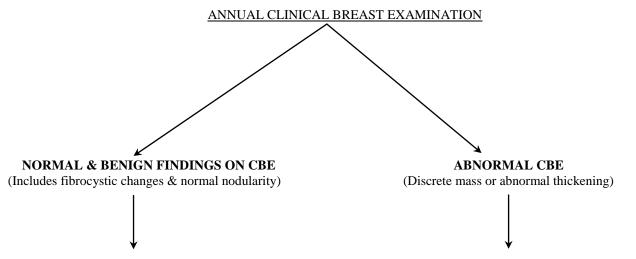
Category 5: Highly Suggestive of Malignancy

There is probability of cancer. Refer to a surgeon for further evaluation. Counsel the patient on the results of the mammogram and assure that the arrangements are made for the surgical consultation.

Category 6: Known Biopsy-Proven Malignancy-Appropriate Action Should Be Taken

This category is reserved for lesions identified on the imaging study with biopsy proof of malignancy prior to definitive therapy.

ALGORITHM FOR BREAST CANCER SCREENING FOLLOW-UP



- 1. REPEAT CBE IN ONE YEAR &
- 2. ANNUAL SCREENING MAMMOGRAM IF AGE 40 AND OLDER
- 3. IF SCREENING MAMMOGRAM IS ABNORMAL, PATIENT TO BE NOTIFIED WITHIN 10 DAYS OF RECEIVING THE RESULT OR WITHIN 30 DAYS OF THE PROCEDURE (whichever comes first)
- 4. A FINAL DIAGNOSIS OBTAINED WITHIN 60 DAYS OF DETECTION OF THE ABNORMALITY (from date screened)
- 5. OBTAIN SCREENING MAMMOGRAM WRITTEN REPORT WITHIN 60 DAYS OF THE PROCEDURE

- 1. BREAST ULTRASOUND (ages 29 and under)
- DIAGNOSTIC MAMMOGRAM (ages 30 & older) and ultrasound if needed
- 3. SURGICAL REFERRAL APPOINTMENT WITHIN 3
 WEEKS OF DISCOVERY OF ABNORMAL CBE
 (Regardless of ultrasound and/or mammogram results)
- 4. FINAL DIAGNOSIS OBTAINED WITHIN 60 DAYS OF DETECTION OF ABNORMALITY (from date screened)
- 5. RECORDS TO BE RECEIVED WITHIN 60 DAYS OF CONSULT/PROCEDURES
- FOLLOW RECOMMENDATIONS OF SURGEON AND/OR RADIOLOGIST

MOBILE MAMMOGRAPHY SCREENING GUIDELINES

A requirement of the Kentucky Women's Cancer Screening Program (KWCSP), as previously noted in the PHPR, is to provide all income eligible women at least minimal services that include a health history, physical examination (including CBE, Pap and bimanual pelvic examination) and anticipatory guidance/counseling.

With the expansion of the number and availability of mobile mammography units and the program's goal of increasing the numbers of income eligible women screened, it is necessary to address community mammography screenings arranged for or conducted by the LHD.

It is *strongly recommended* that women have the minimum requirements including a clinical breast examination, Pap test, and pelvic examination *prior to* obtaining a mobile mammogram screening. However, it is understood that there are circumstances making this impractical. Examples of such circumstances may be the inability to get patients scheduled in the LHD clinics prior to the date the mobile unit is available, inadequate facilities or the lack of personnel available on the given screening day to perform examinations.

The following are the minimal requirements necessary to comply with the KWCSP guidelines to receive reimbursement for community mobile mammography screenings that are restricted to women ages 40 and older that are income eligible and who lack insurance.

PATIENT HISTORY

- Completion of ACH-16 that includes age, breast symptoms, family or personal history of breast cancer, previous breast biopsy, and date of last mammogram.
- Consent for services (CH-5).

EXAMINATION

- Clinical breast examination using the MammaCare technique.
- Client with an abnormal CBE would not have screening mammogram on mobile mammography unit but must be referred for diagnostic mammogram and surgeon referral.

COUNSELING/APPOINTMENT

- Minimal documentation in the medical record must include the patient has been counseled on the importance of
 monthly BSE, yearly CBE with mammogram and annual Pap test with pelvic. The patient may either be given
 an appointment to return to the clinic for completion of the minimal examination or given a number to call and
 make an appointment.
- The appointment for completion of the minimal requirements must be made within 60 working days of the date of the mobile mammogram screening.
- Once the patient keeps the appointment, routine protocols are to be followed.
- If the patient fails to keep the appointment for completion of the examination, appropriate follow-up must be provided.
- If the patient refuses an appointment or otherwise does not have the minimal requirements, the LHD must make an intensive effort to assure that she receives the services, meeting those requirements. Those efforts must be detailed in the patient's chart. Evidence of those efforts is necessary in order for KWCSP to continue reimbursement for screening mammograms in the community setting.

CERVICAL CANCER SCREENING & FOLLOW-UP

Routine periodic screening encourages early identification of precancerous conditions of the cervix and early stage diagnosis of cervical cancer. Most cervical cancer can be PREVENTED with detection and early treatment of precancerous lesions.

A. CERVICAL CANCER RISK FACTORS

- 1. History of HPV and/or Dysplasia
- 2. Multiple (3 or more) sexual partners in lifetime
- 3. A sex partner with multiple sex partners
- 4. A sex partner who has had a partner with HPV/dysplasia/cervical cancer
- 5. Cigarette smoking (any amount)
- 6. Beginning sexual intercourse at a young age (age 18 or less)
- 7. History of 2 or more sexually transmitted infections
- 8. Intrauterine exposure to diethylstilbestrol (DES)
- 9. Infrequent screening (≥5 years since last Pap)
- 10. Immunosuppressed (HIV/AIDS, diabetes, transplant recipient, chronic steroid use, auto-immune disorders)

B. <u>CERVICAL SCREENING HISTORY</u>

- 1. Elicit date and result of last Pap test
- 2. Determine if a previous history of an abnormal Pap and/or HPV
- 3. Determine if history of a previous colposcopy & biopsy and/or treatment
- 4. Screen for risk factors (listed above)
- 5. Screen for history of abnormal bleeding patterns

C. CERVICAL CANCER SCREENING GUIDELINES

- 1. Annual Pap tests beginning 3 years after the onset of vaginal intercourse or no later than 21 years of age, whichever comes first (may be done earlier at clinician's discretion)
- 2. Perform Pap test before Genprobe specimens, wet mounts, or pelvic examination
- 3. Reschedule Pap test if patient is on her menses
- 4. Use only warm water to lubricant the speculum (No lubricants such as K-Y Jelly)
- 5. The entire portio of the cervix must be visualized to obtain an adequate specimen
- 6. The sample from the portio should be taken first followed by the endocervical sample
- 7. The collected material should be applied uniformly to the slide without clumping and rapidly fixed to avoid air-drying which results in artifact and unsatisfactory specimens. (Place collected material immediately in the liquid fixative container if doing a liquid-based Pap such as ThinPrep)
- 8. For DES exposed patients, a smear from the upper two thirds of the vagina should be obtained in addition to the cervix on an annual basis
- 9. In those patients who are post hysterectomy:
 - a. With a cervical stump continue annual cervical Pap tests
 - b. Without a cervical stump:
 - Cessation of Screening: Women who have had a hysterectomy with removal of the cervix for benign reasons (benign gyn disease such as fibroids) and with no history of abnormal or cancerous cell growth may discontinue routine cytology testing (Pap tests). Women with a total hysterectomy still need to have annual vulvar/vaginal exam, CBE, and mammogram visits.

- Exceptions of cessation: Women with the following conditions should be screened annually: immunosuppression (HIV infection), history of cervical cancer or dysplasia, DES exposure or unknown Pap test screening history.
- 10. Always complete the laboratory form in its entirety including LMP, contraceptive method, HRT, and previous abnormal Pap tests or diagnostic/treatment procedures.

D. THE BETHESDA 2001 SYSTEM

The Bethesda System for reporting cervical and/or vaginal cytology is the recognized system for reporting results. The LHD is required to contract with a laboratory that uses this system of reporting. The state computerized reporting options for Pap test findings, and the protocols for management of abnormal findings are based on the Bethesda 2001 System.

SPECIMEN ADEQUACY

Satisfactory Unsatisfactory

GENERAL CATEGORIZATION

Negative for Intraepithelial Lesion or Malignancy (NIL) Epithelial Cell Abnormality

NEGATIVE FOR INTRAEPITHELIAL LESION OR MALIGNANCY

NEGATIVE FOR INTRAEPITHELIAL LESION OR MALIGNANCY WITH:

Presence of Organisms

Trichomonas

Candida

Shift in vaginal flora suggestive of bacterial vaginosis

Bacterial morphology consistent with Actinomyces

Cellular changes consistent with Herpes simplex virus

Reactive cellular changes

Inflammation

Radiation effects

IUD effects

Metaplasia (normal)

Atrophy

EPITHELIAL CELL ABNORMALITIES PRESENT

Squamous Cell Abnormality

Atypical Squamous Cells of Undetermined Significance (ASC-US)

Atypical Squamous Cells cannot exclude a High-grade lesion (ASC-H)

Low Grade Squamous Intraepithelial Lesion (CIN I, Mild Dysplasia, HPV) (LSIL)

High Grade Squamous Intraepithelial Lesion (CIN II, CIN III, Moderate Dysplasia, Severe Dysplasia,

Carcinoma-In-Situ/CIS) (HSIL)

Squamous Cell Carcinoma

GLANDULAR CELL ABNORMALITY (AGC)

Atypical endocervical, glandular or endometrial cells Adenocarcinoma-In-Situ or Adenocarcinoma

CERVICAL CANCER SCREENING & FOLLOW-UP

(continued)

E. PATIENT EDUCATION ON CERVICAL HEALTH

1. Counseling on cervical cancer risk factors and risk reduction (including smoking cessation) at the initial and annual screening visits is required.

2. If Pap test results reveal HPV or dysplasia, the patient is to be counseled on HPV and smoking (as a cofactor in developing cervical cancer). These patients must have documented counseling as appropriate.

F. FOLLOW-UP

- 1. Patients with abnormal Pap test shall be notified within 10 working days from the date the Pap test is received at the clinic.
- 2. Referral appointments must be made within 3 weeks (21 days) of the clinic receiving the abnormal Pap test result. Any delay in meeting this timeframe must be documented in the patient's medical record, including any "1st available" appointment
- 3. A final diagnosis must be made within 60 days of the Pap test screening. The final diagnosis is based on colposcopy and biopsy results.
- 4. Results of referrals including colposcopy, biopsy path reports, cryotherapy, LEEP procedure and pathology reports, CKC procedure and pathology reports, and Laser treatment documentation must be received within 60 days of the procedure.
- 5. The month and year the next Pap test is due is to be documented on the progress note.

G. ABNORMAL PAP TEST REFERRAL AND MANAGEMENT

- 1. Local health departments will provide (either onsite or by offsite provider) for diagnostic evaluation of the following Pap results:
 - a. High Grade Squamous Intraepithelial Neoplasia (CIN II, CIN III, CIS).
 - b. Atypical Glandular (Includes atypical endocervical and atypical endometrial) Cells of Undetermined Significance (AGC)
 - c. Squamous Cell Carcinoma or Carcinoma-In-Situ
 - d. Adenocarcinoma-In-Situ or Invasive Adenocarcinoma
 - e. Low Grade Intraepithelial Neoplasia (CIN I, Condyloma) (LSIL)
 - f. ASC-H (Atypical Squamous Cells: Cannot Exclude High-Grade SIL)
 - g. Atypical Squamous Cells of Undetermined Significance (ASC-US)
 (For women 21 and over with ASC-US or greater on either 6 or 12 mo. repeat Pap.
 For adolescent women 20 and younger with ASC-US or greater on repeat 12 month Pap.)
- 2. All colposcopy providers are expected to have at least an 85% correlation between the Pap and biopsy result
- 3. The contracted provider should review the cytology, colposcopy, and histology results when no lesion or only biopsy-confirmed CIN 1 is identified after coloposcopy in women with HSIL Pap test results. If the review yields a revised interpretation, management should follow American Society for Colposcopy and Cervical Pathology (ASCCP) guidelines for the revised interpretation; if a cytological interpretation of HSIL is upheld or if review is not possible, a diagnostic excisional procedure (e.g., LEEP) is preferred in non-pregnant patients.
- 4. ADOLESCENT (females 20 years and younger) refer for colposcopy for HSIL Pap results. Immediate LEEP is unacceptable.
- 5. *Benign* glandular cells in a post hysterectomy female is normal and does not require further evaluation unless the cells are "atypical glandular".
- 6. If a negative (for intraepithelial lesion or malignancy) Pap test is received without endocervical cells or lacking a transformation zone (TZ), repeat the Pap within 6 months if: a) the patient has a prior Pap result of ASC-US or greater without 3 negative follow-up Pap test results (at least one of which contained an EC/TZ component) b) a previous Pap with unexplained glandular abnormality c) a positive high-risk/oncongenic human papillomavirus (HPV) test within 12 months d) clinician inability to clearly visualize the cervix or sample the endocervical canal e) immunosuppression f) insufficient previous screening (not participating in at least biennial screening). Otherwise, repeat at next annual examination.
- 7. Refer patient if abnormal cervix or polyps visualized.
- 8. A result of "endometrial cells in a woman past age 40" requires a consult with the contracted provider if she is having abnormal bleeding or is post menopausal and not using hormone replacement therapy; otherwise repeat Pap test at next annual visit.

H. TREATMENT

1. Patients that have been screened/diagnosed through KWCSP may be eligible for treatment funds (BCCTP) if diagnosed with pre-cancer/cancer of cervix (includes endocervical). For information and forms related to BCCTP, please refer to their website at http://chfs.ky.gov/dms/bcctp.

- 2. Verify patient's identity by viewing the patient's driver license. Contact the Department for Medicaid Services at 502-564-6204 for citizens born in Kentucky to obtain verification of citizenship. Other patients will need to contact Vital Statistics in their state of birth in order to obtain an original birth certificate. A passport may also be used for documentation of both identity and citizenship. For more information about the citizenship documentation requirement, go to: http://www.cms.hhs.gov/MedicaidEligibility/ProofofCitizenship
- 3. Complete Pre-Screening Eligibility Form.
- 4. Complete application and call Medicaid for confirmation number.
- 5. Enter per Web application (like P.E.). The original signed application, Pre-screening Eligibility Form and proof of identity and citizenship should be maintained in the patient's chart in the administrative section.

GUIDELINES FOR COLLECTING A CERVICAL SPECIMEN FOR PAP TESTING

Physicians, Nurse Practitioners, Physician Assistants, and Registered Nurses who have received formal training and certification through the Department for Public Health Breast and Cervical Cancer Screening Program may perform Pap tests and pelvic examinations.

A. Ideal conditions for collecting a Pap test specimen

- 1. Patient is NOT on her menses
- 2. Cervix is NOT contaminated with lubricants, creams, infection, or semen
- 3. Do not lubricate the speculum with anything other than warm water
- 4. The patient has NOT douched within the past 48 hours
- 5. Cervix does NOT have abrasions from contraceptives, douching, or sex
- 6. Pap test should be taken before Genprobe or wet mount specimens
- 7. Pap test done prior to the pelvic examination
- 8. The entire portio of the cervix must be visualized
- 9. The portio sample should be taken first, followed by the endocervical sample
- 10. The collected material should be applied uniformly to the slide without clumping and rapidly fixed to avoid air-drying which results in artifact and unsatisfactory specimens (If doing a liquid based test such as ThinPrep, the material should be collected on a cervical broom and immediately placed into the liquid fixative).

B. Instruction to the Patient

- 1. Do NOT douche, have sex, or put anything into the vagina for at least 48 hours prior to the Pap test.
- 2. Make the appointment for the Pap test 1–2 weeks after the menstrual period.
- 3. Annual Pap tests recommended beginning 3 years after the onset of vaginal intercourse or no later than 21 years of age (may be done earlier at clinician's discretion)

C. Laboratory equipment needed (usually provided by the contracted lab)

- 1. Glass slides with frosted ends
- 2. Ayre spatula for the ectocervical component (plastic or wooden)
- 3. Endocervical brush (or cotton swab if pregnant)
- 4. Cervical broom
- 5. Fixative (either spray or liquid; hairspray not to be used)
- 6. Mailers or transport materials, collection and report forms

D. Instruction to the Provider

- 1. Obtain Pap specimen BEFORE wet mounts, Genprobe, etc.
- 2. Every Pap test report shall have the date received recorded on the hard copy and the nurse initial that she/he has reviewed prior to entering the results in the PSRS system or placing the report into the patient's medical record.
- 3. A tracking system is required to account for all tests.
- 4. Lab forms must be complete including LMP, previous abnormal Paps, and other as required by the lab. This assists the lab in the interpretation of the test.
- 5. Alternative positioning of the patient, other than lithotomy, may be necessary for disabled individuals.
- 6. If you have difficulty locating the cervix you may need to use a larger speculum, digitally locate the cervix, or have a second provider attempt. Gentleness and respect for the patient should always be the unspoken rule.
- 7. If the guidelines require follow-up Pap test, DO NOT repeat prior to the recommended time to allow time for the cells to regenerate.

MANAGEMENT OF ABNORMAL PAP TEST RESULTS

(Numbers correspond to PSRS submission)

#1 SATISFACTORY / NEGATIVE FOR INTRAEPITHELIAL LESION

- Repeat in 1 year in those women with a cervix
- Repeat in women without a cervix as indicated (see under Cervical Cancer Screening guidelines) SATISFACTORY/ NEGATIVE FOR INTRAEPITHELIAL LESION WITH PRESENCE OF ORGANISMS OR REACTIVE CELLULAR CHANGES:
- Clinician consult to decide if treatment is indicated
- Repeat Pap test at next annual

#2 ATYPICAL SQUAMOUS CELLS OF UNDETERMINED SIGNIFICANCE (ASC-US)

- Per ASCCP guidelines, the standard of care is that the woman 21 years and older can be referred for repeat Pap in 6 and 12 months or referral for immediate colposcopy. Contact the contracted provider to discuss the plan of care for follow-up. Document the provider's order on the CH3-A.
- Please note that another standard of care, per ASCCP, is high-risk HPV DNA testing.

 The HPV DNA testing CPT code, 87621, is a reimbursable procedure if used in the following cases for women 30 and over: 1a) Follow-up of an ASC-US result from the screening exam; 1b) Surveillance at one year following an LSIL Pap test and no CIN 2, 3 on colposcopy-directed biopsy.
- If testing for High Risk HPV DNA is done:
 - o Is negative, then repeat Pap test in 1 year
 - Is positive, then refer for colposcopy.
- ASC-US or greater result on either 6 or 12 month repeat Pap requires colposcopy evaluation
- If both tests are negative, return to routine screening
- **ADOLESCENT** (females 20 years and younger) repeat Pap at 12 months.
 - o If repeat Pap (at 12 months) is less than HSIL repeat Pap at 12 months later.
 - o If repeat Pap at (12 months) is HSIL or greater, refer for colposcopy.
 - o If second repeat Pap (at 24 months) is negative, return to routine screening.
 - o If second repeat Pap (at 24 months) is ASC-US or greater, refer for colposcopy.

#3 ATYPICAL SQUAMOUS CELLS CANNOT RULE OUT HIGH GRADE (ASC-H)

Refer for colposcopy evaluation and biopsy when indicated.

#4 LOW GRADE INTRAEPITHELIAL NEOPLASIA (CIN I, Mild dysplasia, HPV) (LSIL)

- Refer for colposcopy evaluation for women 21 and over.
- **ADOLESCENT** (females 20 years and younger) repeat Pap at 12 months.
 - If repeat Pap is less than HSIL repeat Pap at 12 months later. Refer to ASCCP for further guidelines
 - o If repeat Pap (at 12 months) is HSIL or greater, refer for colposcopy
 - If second repeat Pap (at 24 months) is negative, return to routine screening.
 - o If second repeat Pap (at 24 months) is ASC-US or greater, refer for colposcopy.

#5 HIGH GRADE INTRAEPITHELIAL NEOPLASIA (CIN II, CIN III, Moderate-Severe dysplasia, or carcinoma-in-situ) (HSIL)

- Refer for colposcopy evaluation or LEEP.
- The contracted provider shall perform a review of the cytology, colposcopy, and histology results when no lesion or only biopsy-confirmed CIN 1 is identified after colposcopy in women with HSIL Pap test reports. If the review yields a revised interpretation, management should follow guidelines for the revised interpretation; if a cytological interpretation of HSIL is upheld or if review is not possible, a diagnostic excisional procedure (e.g., LEEP) is preferred in nonpregnant patients.
- **ADOLESCENT** (females 20 years and younger) refer for colposcopy for HSIL Pap results. Immediate LEEP is unacceptable.

#6 SQUAMOUS CELL CARCINOMA

• Refer to a qualified provider

#7 ADENOCARCINOMA OR ADENOMA CARCINOMA-IN-SITU

• Refer to a qualified provider

#8 UNSATISFACTORY

• Repeat Pap *between* 8–16 weeks (2–4 months)

#9 ATYPICAL GLANDULAR CELLS OF UNDETERMINED SIGNIFICANCE (AGC)

- Atypical Endometrial Cells: Refer for colposcopy with ECC. Endometrial biopsy is also indicated. Consider HPV DNA testing for a Pap result of Atypical Glandular Cells; however KWCSP does not reimburse for HPV DNA testing for Atypical Glandular Cells on a Pap result.
- All Subcategories (except atypical endometrial cells): Refer to contracted providers for colposcopy with ECC, HPV testing and endometrial sampling if age 35 and older or at risk for endometrial neoplasia (includes abnormal vaginal bleeding or conditions suggesting chronic anovulation).
- HPV DNA testing will be reimbursed for all subcategories of AGC except Atypical Endometrial Cells if age 35 and older or at risk for endometrial neoplasia.

The 2006 Consensus Guidelines for cervical follow-up are on the American Society for Colposcopy and Cervical Pathology website at http://www.asccp.org/.

FOLLOW-UP PAP TESTS AFTER COLPOSCOPY EVALUATION OR TREATMENT

A. POST COLPOSCOPY PLAN: OBSERVATION FOR NEG, ASCUS, OR LSIL BIOPSY

- 1. Following a patient with Pap tests only (that has had confirmation of LSIL with cervical biopsy) has become an acceptable standard of care. To avoid unnecessary procedures (and their possible adverse effects) clinicians following standardized guidelines are now choosing not to treat these patients with Cryotherapy, Laser, or LEEP. Observational management is acceptable unless the lesion extends into the endocervical canal, the Pap test remains ASC-US or progresses to a higher-grade lesion, or the lesion does not spontaneously resolve after 18–24 months.
- 2. For women being followed with observation for LSIL (confirmed with the diagnostic colposcopy and biopsy) a Pap test shall be repeated at 6 months and 12 months. If either repeat Pap is ASCUS or greater refer for colposcopy. If Pap test returns to normal at both 6 and 12 months or HPV DNA testing at 12 months is normal, return to routine screening. If HPV testing is positive refer for colposcopy. KWCSP does not reimburse for HPV DNA testing for a LSIL Pap result.
- 3. Follow-up colposcopy cannot be paid for by the KWCSP outside of the PHPR protocols.
- 4. Observation only is not the standard of care for women age 21 and over with biopsy confirmed high-grade lesions.
- 5. If the colposcopist prefers to follow the patient with additional colposcopy examinations and/or perform their own Pap tests it will be at the patients's expense and not covered by KWCSP. The health department will still be responsible for obtaining copies of the Pap tests performed outside of the clinic.

B. POST COLPOSCOPY PLAN: FOLLOWING TREATMENT

- 1. If the patient has had Cryotherapy, Laser, LEEP, or a cold knife conization (CKC) a Pap test will be repeated at the health department every 4–6 months X 1 year and then every 6 months X 1 year. (If abnormal result, refer to Management of Abnormal Pap Test Results)
- 2. Regarding patient's post total hysterectomy (with removal of the cervix and uterus): Women without knowledge and/or documentation of prior Pap test results and those with an established history of high-grade squamous dysplasia (CIN 2–3) or cervical cancer prior to the hysterectomy should be screened at 4–6 month intervals (same as in #1 above treatments).
- 3. If the provider and patient make a decision to have the Pap tests performed at the physician's office this will be at the patient's expense. The health department will still be responsible for obtaining Pap results from the provider.

DIAGNOSTIC SERVICES

The Kentucky Women's Cancer Screening Program covers most but not all diagnostic services on income eligible women for the screening test results listed below. As a federally funded program, KWCSP is forbidden to use program funds to pay for diagnostic services on women with Medicaid, Medicare, or private insurance.

Mammogram Results (Screening or Diagnostic)

The corresponding number reflects the universal BI-RADS reporting system

- 0 Assessment Incomplete
- 3 Probably Benign
- 4 Suspicious Abnormality
- 5 Highly Suggestive of Malignancy

Abnormal Clinical Breast Examination

Includes discrete masses or abnormal nipple discharge but excludes normal nodularity and/or fibrocystic changes

Pap Test Results

The corresponding number reflects reporting used in PSRS

- #2 ASC-US x2 consecutive
- #3: ASC-H
- #4: Low Grade Squamous Intraepithelial Lesion-LSIL
- #5: High Grade Squamous Intraepithelial Lesion HSIL
- #6: Squamous Cell Carcinoma
- #7: Adenocarcinoma or Adenocarcinoma-In-Situ
- #9: AGC (Atypical Glandular Cells of Undetermined Significance)

The following page is a list of the screening and diagnostic procedures covered by the KWCSP. They are listed by CPT code in numerical order. These procedures must be provided for all women enrolled in the program who meet eligibility requirements either on-site (if applicable) or with a contracted provider. To make best use of limited resources, it is necessary that all cancer screening and preventive visits as well as Pap tests following diagnostics/treatments be performed at the local health department. The following list does not include reimbursement rates and is not intended to replace the "Kentucky Women's Cancer Screening Program Approved CPT Codes and Reimbursement Rates for Breast and Cervical Cancer Screening Follow-up."

REQUIRED DIAGNOSTIC PROCEDURES AS INDICATED BY THE ABNORMAL TEST RESULT

(May be provided either on site or off site as appropriate)

Kentucky Women's Cancer Screening Project Approved CPT Codes

Breast and Cervical Cancer Screening and Follow-up

		Cost Center-
CPT Code	Service Description	Minor Obj
00400 †	anesthesiology, breast follow up (base rate per unit cost)	813-205
00940 *†	anesthesiology, cervical follow up (base rate per unit cost)	813-205
10021	fine needle aspiration without image	813-304
10022	fine needle aspiration with image	813-304
19000	cyst aspiration (puncture)	813-304
19001	cyst aspiration, additional	813-304
19030 *	injection procedure only for ductogram or galactogram	813-304
19100	breast biopsy, needle core – no imaging guidance	813-304
19101	breast biopsy, incisional, open	813-304
19102	percutaneous, needle core, using imaging guidance	813-304
19103	percutaneous, automated vacuum assisted	813-304
19120	excision of breast tissue	813-304
19125	excision of tissue identified preoperatively	813-304
19126	excision of tissue identified preoperatively, additional	813-304
19290	preoperative placement of needle wire	813-304
19291	preoperative placement of needle wire, additional	813-304
19295	image guided placement	813-304
57452	colposcopy of cervix, upper/adjacent vagina	700-305
57454	colposcopy with biopsy of cervix & endocervical curettage	700-305
57455	colposcopy with biopsy of the cervix	700-305
57456	colposcopy with endocervical curettage	700-305
57460	colposcopy with loop electrode excision of cervix	700-305
57461	colposcopy with loop electrode conization of cervix	813-305
57500	biopsy or excision of lesion, with or without fulguration	813-305
57505	endocervical curettage	813-305
57510 *	cauterization of cervix	813-305
57511 *	cryocautery	700-305
57513 *	laser ablation	813-305
57520	conization of cervix	813-305
57522	loop electrode excision	813-305
58100	endometrial biopsy (only when linked with AGUS result)	700-305
58110 *e	endometrial biopsy performed in conjunction with colposcopy	700-305
S0613 *	Clinical Breast Exam	700-110
77052 *	CAD for use with screening mammogram (use in conjunction with 77057)	813-304/308
77053 *	ductogram	813-304
77054 *	ductogram, multiple ducts	813-304
77055	diagnostic mammogram, unilateral	813-304/308
77056	diagnostic mammogram, bilateral	813-304/308
77057	screening mammogram	813-308

Kentucky Women's Cancer Screening Project

Approved CPT Codes

Breast and Cervical Cancer Screening and Follow-up

		Cost Center-				
CPT Code	Service Description	Minor Obj				
G0202 ^d	digital mammography	813-308				
G0204 ^d	diagnostic digital mammography, bilateral	813-304/308				
G0206 d	diagnostic digital mammography, unilateral	813-304/308				
77031	stereotactic localization for breast biopsy	813-304				
77032	preoperative placement of needle wire, interpretation	813-304				
76098	radiologic examination, breast surgical specimen	813-304				
76645	ultrasound (breast echography)	813-309				
76937 *	ultrasonic guidance for cyst aspiration	813-304				
76942	ultrasonic guidance for needle biopsy (use in conjunction with 19000 or 19001)	813-304				
87621 ^a	papillomavirus, human, amplified probe technique (Hybrid Capture II from Digene-HPV Test)	718-305				
88104 *b	cytopathology, fluids, washings or brushings (breast)	718-304				
88141	pap smear, requiring interpretation by physician (abnormals only)	718-305				
88142	pap smear, thin layer preparation, manual screening	718-305				
88143 *	pap smear, thin layer preparation, manual screening and rescreening	718-305				
88164	pap smear, technical component	718-250				
88172	evaluation of fine needle aspiration	813-304				
88173	interpretation and report of fine needle aspiration	813-304				
88174 *	pap smear, thin layer preparation, automated	718-305				
88175	pap smear, thin layer preparation, automated & manual	718-305				
88305	surgical pathology, gross and microscopic examination	813-304/305				
88307	surgical pathology, associated with LEEP or breast excision requiring evaluation of margins	813-305				
88331 *	pathology consultation during surgery, first tissue block, with frozen section(s), single specimen	813-305				
88332 *	pathology consultation during surgery, each additional tissue block with frozen section(s)	813-305				
99201 °	initial-brief evaluation/management	700-201				
99202 °	initial-expanded evaluation/management	700-201				
99203 °	initial-detailed evaluation/management	700-201				
99204 *c	initial-comprehensive evaluation/management	700-201				
99205 *°	complex-evaluation/management	700-201				
99211 °	subsequent-brief evaluation/management	700-201				
99212 °	subsequent-limited evaluation/management	700-201				
99213 °	subsequent-expanded evaluation/management	700-201				
99214 * ^c	subsequent-detailed evaluation/management	700-201				
99215 * ^c	subsequent-comprehensive evaluation/management	700-201				
99385 *°	initial preventative medicine evaluation 21 - 39 yrs	700-201				
99386 °	initial preventative medicine evaluation 40 - 64 yrs	700-201				
99387 * ^c	initial preventative medicine evaluation 65 and older	700-201				
99395 *°	periodic preventative medicine evaluation 21 - 39 yrs	700-201				
99396 °	periodic preventative medicine evaluation 40 - 64 yrs	700-201				
99397 *°	periodic preventative medicine evaluation 65 and older	700-201				
W9201	initial-brief evaluation/management	700				
W9202	initial-expanded evaluation/management	700				
W9203	initial-detailed evaluation/management	700				

Kentucky Women's Cancer Screening Project

Approved CPT Codes

Breast and Cervical Cancer Screening and Follow-up

		Cost Center-
CPT Code	Service Description	Minor Obj
W9204 *	initial-comprehensive evaluation/management	700
W9205 *	complex-evaluation/management	700
W9211	subsequent-brief evaluation/management	700
W9212	subsequent-limited evaluation/management	700
W9213	subsequent-expanded evaluation/management	700
W9214 *	subsequent-detailed evaluation/management	700
W9215 *	subsequent-comprehensive evaluation/management	700
W9385 *	initial preventative medicine evaluation 21 - 39 yrs	700
W9386	initial preventative medicine evaluation 40 – 64 yrs	700
W9387 *	initial preventative medicine evaluation 65 and older	700
W9395 *	periodic preventative medicine evaluation 21 - 39 yrs	700
W9396	periodic preventative medicine evaluation 40 - 64 yrs	700
W9397 *	periodic preventative medicine evaluation 65 and older	700
W0166 *	charge for use of hospital room (outpatient)	813-311
99241	office consultation (minimal level) outside provider	813-201/202
99242	office consultation (low level) outside provider	813-201/202
99243	office consultation (low-moderate level) outside prov.	813-201/202
99244	office consultation (moderate level) outside provider	813-201/202

† Maximum 4 units up to 1 hour

* Covered by State Funds only

a The HPV DNA testing CPT code, 87621, is a reimbursable procedure if used in the following cases for women 30 years and older: 1a) Follow-up of an ASC-US result from the screening exam; 1b) Surveillance at one year following an LSIL Pap test and no CIN 2, 3 on colposcopy-directed biopsy; and 2) In the initial workup of women 35 years and older or at risk for endometrial neoplasia with ATYPLICAL GLANDULAR CELLS OF UNDETERMINED SIGNIFICANCE (AGC) (except atypical endometrial cells), a colposcopy, HPV DNA Test and Endometrial Sampling shall be performed.

b Effective October 1, 2001, this pathology code is not to be used on routine breast cysts (clear fluid/disappears on ultrasound). Only to be used for cases with bloody/abnormal fluid or cysts that does not disappear on ultrasound.

c When this evaluation/management or preventative service is performed in-house by a Registered Nurse, code W920- should be billed instead of 9920- for a new patient and code W921- instead of 9921- for established patients.

d Digital mammography is approved at the conventional film rate per CDC 10/6/05.

e Use code 58110 in conjunction with 57452, 57454-57456, and 57460-57461. List code separately in addition to code for primary procedure.

CASE MANAGEMENT

Tracking and Follow-up Requirements

The Local Health Department (LHD) is accountable for tracking patients with abnormal screening test results regardless of the patient's age, income or insurance status, to ensure that all women receive the necessary rescreening or diagnostic follow-up services to reach a timely final diagnosis and begin treatment. This includes those patients where the screening occurred in another program such as family planning, pediatrics, or prenatal.

Each clinic site is responsible for assigning this tracking responsibility to a Registered Nurse, Advanced Registered Nurse Practitioner or Licensed Practical Nurse. The nurse that assumes this responsibility is referred to as the Nurse Case Manager (NCM).

Prior to assuming the role and responsibilities of NCM with the KWCSP, the nurse must complete the following educational modules on TRAIN; How to Best Utilize the State's Breast and Cervical Cancer Screening and Treatment Programs (Course # 1009091), Cancer Screening and Follow-Up Using the Public Health Practice Reference (Course # 1013695), Kentucky Public Health Nurse Case Management: Helping Women with Abnormal Breast and Cervical Cancer Screening Results (Course # 1013696). These modules are optional for the backup NCM who assumes this role during an absence of the assigned NCM as described below.

The following modules are highly recommended; Who are the Never and Rarely Screened? Kentucky Women Share Insights about the Impact of their Care and How You Can Make the Difference (Part 1 Course # 1010683, Part 2 Course # 1010684).

When there is a staff change for the NCM position, the Nursing or Clinical Supervisor must notify the Clinical Coordinator of the KWCSP at 502-564-3236, as soon as possible. Face-to-face training will be provided to each new NCM by the Clinical Case Management Coordinators assigned to each county.

There must also be another RN, LPN or ARNP trained by the Clinical Coordinator or Case Management Coordinator assigned to your county and knowledgeable about cancer screening follow-up available to assume the Nurse Case Manager's (NCM) role and responsibilities in the event the NCM is absent for more than seven calendar days. A timely diagnosis is crucial to creating positive outcomes in cancer screening.

Tracking and follow-up can be time consuming and therefore it is recommended that professional and support staff work as a team toward this effort. The NCM is required to provide patient contact, counseling, tracking, and follow-up while the support staff may assist the case manager by scheduling appointments, obtaining records, and electronic entry of data. The NCM shall review all patient appointment arrangements and medical records to provide detailed documentation in the Progress Notes of the patient's medical chart. Administrative time is imperative for NCMs to meet program requirements. The NCM should assure that all aspects of the case management process are appropriately documented in the patient's service record.

The NCM must have an organized manual or electronic tracking system in place to assure that patients receive appropriate and timely intervention. It is also strongly recommended that the ACH-58 Case Management Form side (in this section) be used to assist staff with this required tracking and follow-up. (See Administrative Reference for instructions on Data Collection side of form.)

For further testing and management after the initial abnormal result, patients who qualify for KWCSP should be case managed by the local health department according to program guidelines. However, when a patient has a medical home, the patient may be referred back to the primary care physician for follow-up management, after the patient is informed of the abnormal test and need for follow-up. Health departments should have good communication with local medical home providers so that each provider's role and expectations are clear.

A flowchart outlining the case management guidelines can be found at the end of this case management section.

A. Informing the Patient of Abnormal Results

Patients with an abnormal Pap test or mammogram result must be notified within 10 working days from receipt of the abnormal test result or within 30 days from the test date (which ever comes first) following this plan of action:

- Whenever possible, the NCM shall contact the patient by telephone and have her come to the clinic for face-to-face counseling for abnormal test results. It is expected that the clinic has emergency numbers for all "no home contact" patients. Guidance for "no home contact" patients and minors is found in KRS 214.185.
- 2. When the patient comes in to the Health Department for counseling, test results and recommendations for follow-up are reviewed with the patient, options discussed, and a letter explaining the result in writing is given to the patient. Arrangements for follow-up are then made (see Section B). The visit shall be documented in the patient chart.
- 3. If the NCM is unable to make verbal contact with the patient by phone then an attempt to contact the patient by letter on the same day as the unsuccessful phone call is necessary. The letter shall inform the patient about the abnormal test result with instructions to contact the NCM at the health department.
- 4. If the patient does not respond within 10 working days after the letter is mailed, the nurse shall then send a certified letter to the patient informing her of her abnormal test results with instructions to contact the health department.
- 5. If the patient does not contact the health department within 10 working days after the certified letter is mailed a home visit should be attempted on those patients with test results that are potentially "life threatening" (includes a "HSIL" or "ASC-H" result on a Pap test or a "Suspicious Abnormality" or "Highly Suggestive of Malignancy" mammogram result) prior to documenting the patient is lost to follow-up.

B. Follow-up for Abnormal Test Results

All patients with abnormal lab tests need follow-up. Patients who meet eligibility criteria for KWCSP must be referred according to program guidelines to contracted specialists for further testing/evaluation. Other patients may have a medical home (regular source of medical care) outside of the local health department (LHD). The patient's medical home/PCP can be determined at registration.

Medical homes may include private physicians, Passport providers, Primary Care Centers, FQHC's, and Community Health Centers. These providers generally arrange and provide follow-up care for their patients. Each local health department should maintain open communication with primary care providers in their area to be sure there is agreement on roles and expectations for follow-up of patients with abnormal results.

B1. Follow-up Arrangements for KWSCP-eligible Patients

- 1. The NCM will schedule an appointment for the patient with a KWCSP contracted provider for the appropriate follow-up testing or evaluation. A referral letter and reports of the abnormal test results are sent to the contracted provider who will be seeing the patient.
- The NCM tracks to see that the patient showed for the appointment and documents the visit in the patient's chart.
- 3. The NCM collects reports from the contracted provider and makes arrangements for further diagnostic testing as ordered.
- 4. If the patient does not keep an appointment for a scheduled consult appointment, diagnostic procedure, treatment, or follow-up/repeat Pap, a certified letter will be sent to the patient within 10 working days of the missed appointment. No further follow up tracking is needed for these patients.
- 5. If the patient is a minor with a potentially life-threatening test result (includes a "HSIL" or "ASC-H" result on a Pap test or a "Suspicious Abnormality" or "Highly Suggestive of Malignancy" mammogram or ultrasound result) and cannot be contacted, the parent or guardian must be contacted. Minors shall be made aware of this policy at the screening visit.
- 6. All attempts of patient contact shall be documented in the progress notes (CH3A).

B2. Follow-up Arrangements for Patients with a Medical Home

1. The NCM will schedule an appointment for the patient with their PCP for the appropriate follow-up testing or evaluation. A referral letter and reports of the abnormal test results are sent to the Primary Care provider who will be seeing the patient.

- **NOTE:** It is imperative that the PCP is informed of any of their patient's abnormal test results. This will allow the PCP to assure that the patient receives the appropriate follow-up care.
- 2. The NCM tracks to see that the patient showed for the appointment and documents the visit in the patient's chart. Once the patient has kept her follow-up appointment with her PCP, the responsibility for further follow-up is transferred from the LHD to the PCP. The PCP assumes the follow-up care for their patient.
- 3. If the patient does not keep the scheduled appointment with her PCP for follow-up on her abnormal test result, a certified letter will be sent to the patient within 10 working days of the missed appointment. A copy of the certified letter is to be sent to the PCP.
- 4. If the patient does not contact the health department within 10 working days after the certified letter is mailed, the NCM shall contact the PCP. The NCM must verify that the PCP is aware of the findings and accepts responsibility for patient follow-up.
- 5. If the patient is a minor with a potentially life-threatening test result (includes a "HSIL" or "ASC-H" result on a Pap test or a "Suspicious Abnormality" or "Highly Suggestive of Malignancy" mammogram or ultrasound result) and cannot be contacted, the parent or guardian must be contacted. Minors shall be made aware of this policy at the screening visit.
- 6. All attempts of contact with the patient and PCP shall be documented in the patient's progress notes (CH3A).

B3. Follow-Up Arrangements for Patients with a Medical Home Under Passport

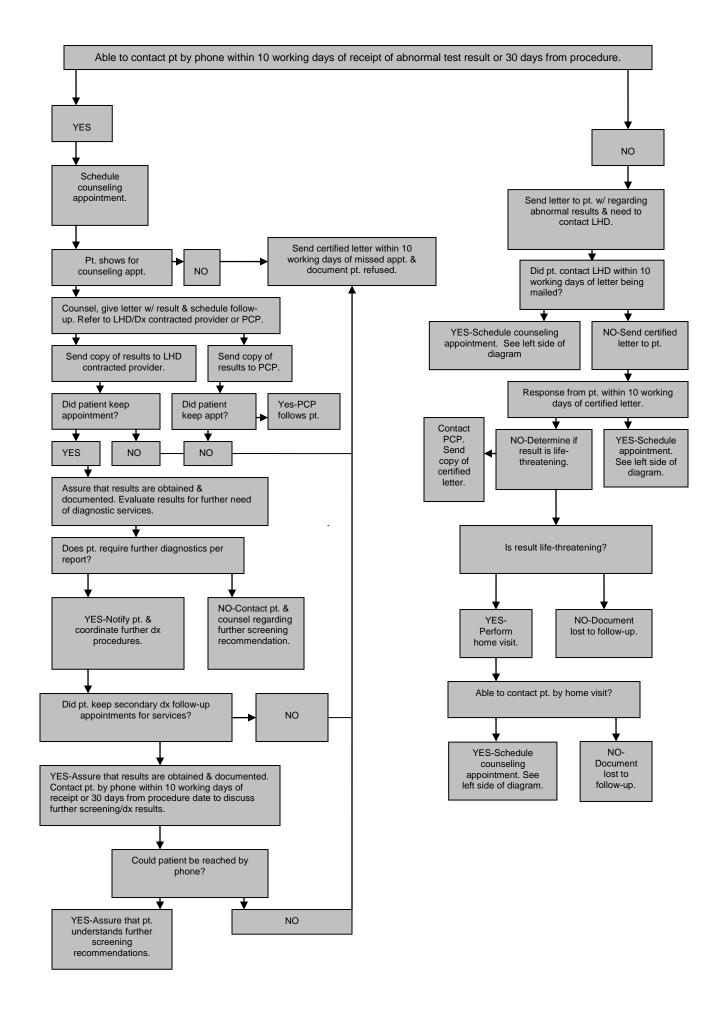
- 1. The NCM will schedule an appointment for the patient with their PCP for the appropriate follow-up testing or evaluation. A referral letter and reports of the abnormal test result(s) are to be sent to the PCP who will be seeing the patient. NOTE: It is imperative that the PCP is informed of any of their patient's abnormal test results. This will allow the PCP to assure that the patient receives the appropriate follow-up care.
- 2. In addition, a letter shall be mailed or faxed to the Passport Case Management Department at 502-585-7997 regarding their beneficiaries with an abnormal test result to inform Passport of the abnormal test results and the need for further follow-up, tracking and monitoring.
- 3. The NCM tracks to see that the patient showed for the appointment and documents the visit in the patient's chart. Once the patient has kept her follow-up appointment with her PCP then the responsibility for further follow-up is transferred from the LHD to the PCP. The PCP assumes the follow-up care for their patient.
- 4. If the patient does not keep the scheduled appointment with her PCP for follow-up on her abnormal test result(s), a certified letter will be sent to the patient within 10 working days of the missed appointment. A copy of the certified letter is to be sent to the PCP.
- 5. If the patient does not contact the health department within 10 working days after the certified letter is mailed, the NCM shall contact the PCP. The NCM must verify that the PCP is aware of the findings and accepts responsibility for patient follow-up.
- 6. If the patient is a minor with a potentially life-threatening test result (includes a "HSIL" or "ASC-H" result on a Pap test or a "Suspicious Abnormality" or "Highly Suggestive of Malignancy" mammogram or ultrasound result) and cannot be contacted, the parent or guardian must be contacted. Minors shall be made aware of this policy at the screening visit.
- 7. All attempts of contact with the patient and PCP shall be documented in the patient's progress notes (CH3A).

C. Other Situations:

<u>Patients</u> who are not KWCSP eligible and do not have a medical home: Local Health Departments may screen some patients who are not eligible for KWCSP and do not have a medical home. Efforts should be made to find the patient a medical home. If that is not possible, then the LHD may manage these patients following KWCSP protocols and providers. Efforts should be made to find other resources for financial assistance in these circumstances as they would not be covered by the KWCSP.

Work-up Refused: occurs when a patient has been notified and counseled (by phone or in person) regarding an abnormal result and either fails to keep a referral appointment for diagnostics/treatment or verbalizes her desire not to seek follow-up. The date of final contact should be noted in the service record (CH3A) and on ACH-58 Data Collection Form side (women 40–64 years old).

<u>Lost to Follow-up</u>: occurs when unable to inform and counsel the patient, either by phone or in person, regarding an abnormal test result. The date of the final contact attempt should be noted in the service record (CH3A) and on ACH-58 Data Collection Form side (women 40–64 years old).



KENTUCKY WOMEN'S CANCER SCREENING PROGRAM DATA COLLECTION FORM

The following information must be entered electronically & is REQUIRED on ALL women ages 40–64 without third party coverage (Medicaid, Medicare or private health insurance) and are below 250% federal poverty guidelines. For ALL valid codes, please refer to the Administrative Reference and KWCSP Minimum Data Elements Manual.

Patient Name	Visit Date: / / / MM DD YYYY Provider ID# _ (Service Provider: Please fill out each box on form and retain for 10 years.)					
Section A. Breast Screening History Data Breast Symptoms? (self-reported) () 1. Yes () 2. No Prior Mammogram? () 1. Yes () 2. No If yes, Date:/	Section A. Cervical Screening History Data Cervix Present? () 1. Yes () 2. No (Do not report vaginal Pap test data) Prior Pap Test? () 1. Yes () 2. No If yes, Date: / MMM YYYY					
Section B. Breast Screening Data Clinical Breast Exam (CBE) performed at this visit? Yes, (CBE Results): () 1. Normal () 2. Abnormal CBE Date:/	Section B. Cervical Screening Data					
Section C. Mammogram Results Data Mammogram Results (BI-RADS): If BI-RADS 0, Prior Film Comparison Required? () 1. Yes () 2. No Date of Mammogram: (MMDDYYYY) Diagnostic procedures (Work-up) planned: () 1. Yes () 2. No () 3. Not yet determined.	Pap test results: () 1. Positive () 2. Negative Section C. Pap Test Results Data Pap test results: Pap test date:/					
Section D. Breast Diagnostic (Work-up Planned) Procedures Procedure 1. Diagnostic Mammogram (Additional Views) 2. Ultrasound 3. Film Comparison 4. Surgical Consult 5. Fine Needle/ Cyst Aspiration 6. Breast Biopsy/Lumpectomy 7. Other Diagnostic procedures 7a. Other Diagnostic (report CPT code) To. Other Diagnostic (report CPT code) Section E. Breast Diagnostic/Follow-up Data 1. Status of Breast Diagnosis: () 1. Work-up complete* () 2. Work-up pending () 3. Lost to follow-up* () 4. Work-up refused* () 5. Treatment pending () 6. Breast Diagnosis: () 1. Treatment Status: () 1. Treatment started* () 2. Treatment pending () 3. Lost to follow-up* () 4. Work-up refused* () 5. Treatment rot needed* () 6. Treatment required 2. Date of Final Diagnosis: () 1. Ductal Carcinoma in Situ (Stage 0) () 2. Invasive Breast Cancer () 3. Breast Cancer not diagnosed () 4. Lobular Carcinoma in Situ (Stage 0)	Section D. Cervical Diagnostic (Work-up Planned) Procedures Procedure 1. Colposcopy with Biopsy and/or ECC 2. Colposcopy without Biopsy 3. Loop Electrode Excision Procedure (LEEP) 4. Endocervical Curettage alone (ECC) 5. Cold Knife Cone 6. GYN Consult 7. Others Diagnostic procedures 7a. Other Diagnostic (report CPT code) 7b. Other Diagnostic (report CPT code) Section E. Cervical Diagnostic/Follow-up Data 1. Status of Cervical Diagnosis 4. Treatment Status: () 1. Work-up complete* () 2. Treatment pending () 3. Lost to follow-up* () 4. Work-up refused* () 5. Treatment refused* () 6. Treatment refused* () 7. Date of final Diagnosis: Section Final Diagnosis: Section Final Diagnosis: Section Final Diagnosis: () 1. Normal/Benign reaction/Inflammation () 2. Treatment Status: MM DD YYYY 3. Final Cervical Diagnosis: () 1. Normal/Benign reaction/Inflammation () 7. Others: (Describe) () 2. HPV/Condylomata/Atypia () 3. CINII/Mid dysplasia (biopsy diagnosis) () 4. CINII/Moderate dysplasia/Carcinoma in Situ (stage 0) () 6. Invasive Cervical Carcinoma (biopsy diagnosis)					
	PASTE "C Label" HERE SSN: Health Dept. Section A. Breast Screening History Data Breast Symptoms? (self-reported) () 1. Yes () 2. No Prior Mammogram? () 1. Yes () 2. No If yes, Date:					

KENTUCKY WOMEN'S CANCER SCREENING PROGRAM DATA COLLECTION FORM

Patient 1	Vame			
	First	M.I.	Last	
	PASTE "C	Label"	HERE	
SSN:	He	alth Dept.		

KENTUCKY WOMEN'S CANCER SCREENING CASE MANAGEMENT FORM The following information is RECOMMENDED to be collected on ALL women with an Abnormal PAP/CBE/Manimogram regardless of age.

BREAST CANCER RISK FA Female age 40 or older 1" degree relative (mother Personal history of breast of the personal history of benign Menarche prior to age 12 Menopause after age 52 No pregnancies or 1" preg Obesity and/or high fat die	, sister, daughter) wi cancer breast condition nancy after age 30		ounseled on breast cancer risk age 50	xs// MM DD YYYY
CERVICAL CANCER RISK History of HPV and/or cer Smoker Intrauterine exposure to D Intercourse prior to age 18 History of 3 or more sex p Partner with many sex par HIV/AIDS positive or History of two or more sex Other Immuno-compromis	vical dysplasia ES partners in lifetime tners or a partner wi kually transmitted in	th cervical dysplasia/car fections in lifetime	ounseled on cervical cancer n	isks / / MM DD YYYY
Date of Annual/Initial Exam:			nic Illnesses	
_	AM DD YYY			
CBE: Normal Abr	normal	PAP Test: Normal_	Abnormal	Result
Date of Mammogram: /	/	Result: BI-RADS clas	sification or N/A	
Certified Letter Date Home Visit Date Face to Face Date	& Response & Response & Response & Response & Response		BNORMAL RESULTS	
		DATE	Elline of the	
PROCEDURE	DATE OF PROCEDURE	RECORDS RECEIVED	FINDINGS and F	OLLOW-UP PLANS
Diagnostic Mammogram				
Ultrasound				
Surgical or GYN Consult				
Breast Biopsy/Aspiration				
Lumpectomy/Mastectomy				
Chemotherapy/Radiation				
Colposcopy & Biopsy				
Endometrial Biopsy				
Cryotherapy or LEEP				
Cold knife				
cone/Hysterectomy				
Next PAP Due Nurse Case Manager:			t Mammogram Due	ACH-58 (Rev. 02/06)

PAP TEST LOG (ACH-259)

- 1. After the Pap has been completed and processed for mailing, a lab label should be placed on the Pap log.
- 2. The date of the Pap test must be written in the column provided on the Pap log.
- 3. When the Pap results are received, every Pap report must be reviewed, initialed and dated by a nurse as stated in the Public Health Practice Reference.
- 4. The appropriate result code must be determined by the nurse reviewing the Pap report and checked in the results column.
- 5. The results should be entered into the PSRS as appropriate.
- 6. This log may be used as a tickler system for follow-up if desired.

MAMMOGRAM AND ABNORMAL CBE LOG (ACH-100)

- 1. A lab label should be placed on the mammogram log after the patient is scheduled for the exam.
- 2. When the mammogram result is received, it must be reviewed, initialed by a nurse and appropriate BI-RADSTM code checked in the results column.
- 3. Enter into PSRS and supplemented as appropriate.
- 4. The log may be used as the tickler file for follow-up if desired.

MAMMOGRAM AND ABNORMAL CBE LOG

	1,11,11,11	<i></i>
MONTH:		

	CI	BE	Type of Procedure		Type of Procedure			I	Mam	mogı	ram Re	esult		D	iagn	ostic	Eval	uatio	n	
Patient Identification (May use label)	Normal or Abnormal	Date of Mammogram	Screening	Diagnostic	#0 Incomplete	#1 Negative	#2 Benign	#3 Probably Benign	#4 Suspicious Abnormality	#5 Highly Suggestive of Malignancy	#6 Known Biopsy- Proven Malignancy	Date of Surgeon appointment	Further views	Ultrasound	Biopsy	Copies	Date of next mammogram	Final Diagnosis and Comments		

PAP TEST LOG

MONTH:																
Patient Identification (May use label)	Program	Date Pap done	Date received	#1 Negative with or without infection or reactive changes	#2 ASC-US	#3 АЅС-Н	#4 LSIL (CIN I, HPV)	#5 HSIL (CIN II, CIN III, CIS)	#6 Squamous Cell Carcinoma	#7 Adenocarcinoma or AIS	#8 Unsatisfactory	#9 AGC	Date of patient contact	Date of Colposcopy appt.	Diagnostic/treatment records received	Month/Year next Pap due

INSTRUCTIONS FOR USE OF THE BREAST CANCER SCREENING REPORT (ACH-16)

The ACH-16 is used to request and document results of mammograms from the radiology provider. The mammogram narrative report should be kept with the completed ACH-16 and filed together in the medical record. The ACH-16 should be filled out on all women being referred for a mammogram regardless of income, age, or payer status.

TO BE COMPLETED BY LHD

- 1. Enter the name of the LHD requesting the mammogram or diagnostic breast ultrasound.
- 2. Attach a lab label in the place provided.
- 3. Complete items 1–5 with information from the current history.
- 4. Enter the results of the clinical breast examination in item 6.
- 5. Enter the type of mammogram requested, the visit date, and the signature and identification number of the clinical breast examination provider in item 7i.
- 6. Enter the name, address, and telephone number of the contracted surgeon who will be evaluating abnormal test results (or patient's PMD).

TO BE SIGNED BY THE PATIENT

- 1. Have the patient sign the referral section.
- 2. Retain the copy of the form in a tickler file at the LHD to track receipt of the mammogram results. The form should be sent to the radiology facility.
- 3. If desired by the patient, have a release of information (ROI) signed so a copy of the mammogram result can be sent to the patient's family physician.

TO BE COMPLETED BY MAMMOGRAPHY PROVIDER

- 1. Check the one type of mammogram performed in item 8. If a screening mammogram is requested in item 7, a screening mammogram should be performed. If the LHD requests a diagnostic mammogram in item 7, an initial diagnostic mammogram should be performed. When a screening mammogram has been requested and performed and the radiologist has determined the need for additional views, a second ACH-16 should be initiated and Follow-up Diagnostic checked in item 8.
- 2. The applicable BI-RAD category is checked by the radiologist in item 9. Include a description of any negative findings, the date of the mammogram, and the signature of the radiologist.
- 3. Enter the name and address of the agency storing the mammography films.
- 4. The mammography provider keeps a copy of the form.
- 5. A copy of the completed ACH-16 is returned to the LHD.

A LHD nurse shall note results and the patient shall be notified. A copy of the form shall be filed in the medical record with the narrative report attached to it

Kentucky Department for Public Health Breast Cancer Screening Report

LOCAL HEALTH DEPT	
TO BE COMPLETED BY LOCAL HEALTH DEPARTMENT	Lab Label from Patient Services Reporting System
Breast symptoms (self-identified)	
□Yes □No □Unknown	6. Clinical Breast Examination (CBE) Results
2. Previous mammogram	□ Normal Exam/ Nodularity □ Fibrocystic Changes or Other Benign Findings Explain:
3. Previous breast biopsy Yes No Unknown \$\forall \text{If yes, Approximate Month/Year} \] SITE: RIGHT LEFT 4. Patient had breast cancer Yes No Unknown	□ Discrete Lump or Mass □ Discharge (e.g. clear, serous, bloody) □ Nipple or Areolar Scaling □ Skin Dimpling, Retraction □ Focal, Immobile Thickening
♥If yes, Approximate Month/Year/	RIGHT LEFT
5. Sister/mother/daughter breast cancer age ≤50 Yes □No □Unknown	(Findings in BOLD require diagnostic referral)
7. Type of Mammogram Ordered Screening	Initial Diagnostic Diagnostic
	rovider Signature Provider ID
INFORMATION ON SURGEON FOR ANY NEEDED FOLLOW-UP (UNDER LHD CONT	-
Name	
Address	Zip
TO BE SIGNED BY PATIENT	
I have been informed and understand that: I am being refer	rred to
for a mammogram; the results of the x-ray will be reported may be responsible for paying a portion of the charge for th	ne mammogram.
,	Patient Signature and Date
TO BE COMPLETED BY MAMMOGRAPHY PROVIDER	
8. Type of Mammogram Performed 9. Mammog	graphy Results: CIRCLE ONE.
	n College of Radiology BI-RADS
1. Negative	
3. Probably	
☐ Follow-up Diagnostic 5. Highly so	uggestive of malignancy Biopsy-Proven Malignancy
Describe abnormal findings and recommendations for follo	w-up care:
/ X Date of Mammogram Radiologist Signature	
Date of Mammogram Radiologist Signature	<u>₽</u>
Name and address of agency storing mammography films:	

Kentucky Women's Cancer Screening Program Mammography Provider Contract Requirements Fiscal Year 2011 Rev. 02/23/2010

MAMMOGRAPHY PROVIDER REQUIREMENTS

Mammography in accordance with the requirements listed below:

- 1. The Health department will screen patients for eligibility, including income criteria. The Health department will authorize which patients are to receive screening mammograms under this program.
- 2. Facilities performing mammograms shall be accredited by the American College of Radiology Accreditation Program and certified by the federal Food and Drug Administration (FDA).
- 3. A list of radiologists providing interpretation will be provided to the Health department and attached to the contract. Updating this list (additions or deletions) will be the responsibility of the Contractor.
- 4. Each radiologist responsible for interpretation of results will have current continuing education in the field of mammography.
- 5. Interpretation of mammogram and ultrasound results will be recorded on the ACH-16 form, which must be completed, signed and submitted by the health department. Results must be recorded as a single category on the ACH-16 form based on the following categories. (Results of subsequent tests, e.g. additional views, ultrasound, etc. shall be reported separately from the mammogram results.)
 - 0 Assessment Incomplete need additional imaging.
 - 1 Negative.
 - 2 Benign Finding.
 - 3 Probably Benign short interval follow-up indicated.
 - 4 Suspicious Abnormality biopsy should be considered.
 - 5 Highly Suggestive of Malignancy appropriate action should be taken.
 - 6 Known Biopsy Proven Malignancy–Appropriate Action Should Be Taken
- 6. Payment for a screening or a diagnostic mammogram will be made only if specifically ordered by the Health department on the completed and signed ACH-16 form. The Bi-Rads on the ACH-16 form must match the narrative report before payment will be issued.
- 7. It is expected that the percentage of recall indicating need for further diagnostic workup be no more than the national average (less than or equal to 10%).
- 8. The report of the mammogram reading must indicate the name and address of the facility where the x-rays are stored so that the woman and the local health department know where the mammogram films are should they be needed at another location for consultation/referral studies.
- 9. There will be no billing of the patient by any member of the Contractor. For these purposes, Contractor includes cooperating hospital, radiologist, or technician.

Kentucky Women's Cancer Screening Program Pap/Pathology Requirements Fiscal Year 2011

Rev. 02/23/2010

- Facilities performing cytology/histology services shall be certified for Medicaid/Medicare, thus meeting Clinical Laboratories Improvement Act (CLIA) regulations. A copy of Contractor's CLIA-88 Certificate must be included with the signed contract.
- 2) Hospital laboratories shall be accredited by the Joint Council on the Accreditation of Healthcare organizations.
- 3) Cytology results shall be reported to the Health department utilizing the reporting categories for Specimen adequacy

and Results based on the BETHESDA 2001 System as follows:

A. Identification of type of test (conventional or liquid based and noted if the specimen was examined by an

automated device)

- B. Adequacy of the Specimen
 - Satisfactory for interpretation
 - 2. Unsatisfactory (specify reason)
- C. General Categorization (optional)
 - 1. Negative for Intraepithelial Lesion or Malignancy (NIL)
 - 2. Epithelial Cell Abnormality (specify squamous or glandular)
- D. Interpretation/Result
 - Negative for Intraepithelial Lesion or Malignancy (NIL)
 - 2. Negative for Intraepithelial Lesion with the Presence of
 - a. Organisms (identify)
 - b. Reactive Cellular Changes
 - c. Atrophy
 - d. Glandular cells status post hysterectomy
 - e. Endometrial cells in a woman greater than 40 years of age
 - 3. Atypical Squamous Cells
 - a. ASCUS (Undetermined Significance)
 - b. ASC-H (Cannot Rule out High Grade)
 - 4. Low Grade Squamous Intraepithelial Lesion
 - a. LGSIL
 - b. Mild Dysplasia
 - c. HPV
 - c. CIN I

- 5. High Grade Squamous Intraepithelial Lesion
 - a. HGŚIL
 - b. Moderate Dysplasia
 - c. Severe Dysplasia
 - d. CIN II
 - e. CIN III
 - f. Carcinoma-in-Situ (CIS)
- 6. Squamous Cell Carcinoma
- 7. Adeno-Carcinoma/Adeno-Carcinoma-in-Situ
- 8. Unsatisfactory
- 9. Atypical Glandular Cells of Undetermined Significance (AGUS)
 - a. Atypical endocervical cells
 - b. Atypical endometrial cells
 - c. Atypical Glandular of Undetermined Origin
- 4) The Contractor shall provide collection supplies for either conventional or liquid-based Pap tests.
- At ongoing, monthly intervals, the Contractor shall provide the Health department with a list of health department clients whose Pap tests were read and the results of the interpretations, in a format agreed upon by the Health department. All abnormal results shall be clearly indicated by the Contractor to the Health department.
- 6) The Contractor will provide the Health department with a six-month and twelve-month comprehensive profile of findings of Pap test results of health department clients, in a format agreed upon by the Health department. This profile shall include a breakdown of BETHESDA results in the distinct reporting categories listed in #3 above.